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Scott C. Harris FISH & RICHARDSON P.C. 4350 La Jolla Village Drive, Suite 500			BAKER, MAURIE GARCIA	
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Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.

09/699.076

Applicant(s)

Petasis et al

Office Action Summary

Examiner

Art Unit Maurie G. Baker, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filled after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by stetute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) X Responsive to communication(s) filed on Sep 2, 2003 2a) X This action is FINAL. 2b) \square This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213. Disposition of Claims is/are pending in the application. 4) X Claim(s) 12, 18-21, 29, and 34-43 4a) Of the above, claim(s) 34 and 40-42 is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) X Claim(s) 12, 18-21, 29, 35-39, and 43 is/are rejected. 7) Claim(s) is/are objected to. are subject to restriction and/or election requirement. 8) Claims Application Papers 9) \square The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action. 12) The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. §§ 119 and 120 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) \square All b) \square Some* c) \square None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received. 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) The translation of the foreign language provisional application has been received. 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). 5) Notice of Informal Patent Application (PTO-152) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

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DETAILED ACTION

Applicant's Response filed September 2, 2003 (Paper No. 13) is acknowledged.
 Claim 38 was amended and no claims were added or cancelled. Therefore, claims 12, 18-21, 29 and 34-43 are currently pending.

2. Claims 34, 40, 41 and 42 remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected species, there being no allowable generic or linking claim. Claims 12, 18-21, 29, 35-39 and 43 read on the elected species and remain under examination.

Information Disclosure Statement

3. The examiner notes with appreciation the resubmission of the references from the Information Disclosure Statement (PTO-1449) filed June 1, 2001. A signed copy of the PTO-1449 is attached to this action.

Status of Rejections

4. The previous rejection under 35 U.S.C. 112, first paragraph is withdrawn in view of applicant's arguments. The 102/103 rejection is maintained and applicant's arguments are addressed following the rejection. Also, a new rejection, necessitated by applicant's amendment, is set forth in this action.

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Maintained Rejections Claim Rejections - 35 USC § 102/103

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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8. Claims 12, 18-21, 29, 35-39 and 43 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Palfreyman et al (US 4,421,767).

Palfreyman et al disclose collections of compounds (reading on the claimed "combinatorial library") that read directly on the instant formulas 1 and 23. See, compounds of the formulas I, II and III in Palfreyman et al (columns 3-4). The compounds of the reference read on the claims where in the instant formula 23 R¹ & R² = H; R³ = H; R⁹ = aryl; and R¹⁰ & R¹¹ = fluoro, chloro or bromo. The compounds of formulas I and II of Palfreyman et al also read on the instant formulas 1 and 4. The collections of compounds of the reference reads on applicant's definition of a "combinatorial library" (see, instant specification, page 7, lines 14-36).

In the alternative, although Palfreyman et al does not disclose that their collections of compounds (i.e. libraries) are made by the claimed processes, the products of Palfreyman et al would appear to be the same as those recited by the instant claim, regardless of their method of manufacture. See MPEP 2113. Also note that many of the instant claims recite *process limitations only* and thus are non-limiting on the product.

The collection of compounds of Palfreyman et al (reading on the claimed "combinatorial library") meet all of the limitations of the claimed library except for the product-by-process limitations and would either anticipate or render obvious the claimed library. "[E]ven though product-by process claims are

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limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPO 964, 966 (Fed. Cir. 1985).

The examiner respectfully points out that since the claim is drawn to a "combinatorial library", but this product is defined as a product-by-process, that any collection of compounds meeting the structural requirements of the instant claims reads on this product. The <u>process</u> by which the claimed library is made does not appear to lend patentable weight to the claimed invention. One of ordinary skill would expect the library to be the same no matter how it was synthesized.

Response to Arguments

- 9. Applicant's arguments filed September 2, 2003 have been fully considered but are not found persuasive. The examiner's rationale is set forth below.
- 10. Applicant argues that Palfreyman et al do not disclose a "combinatorial library". As stated by the examiner, the collections of compounds of the reference read on applicant's definition of a "combinatorial library" (see, instant specification, page 7, lines 14-36). Specifically, the instant specification, page 7, lines 14-36 recites: that the "term

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"combinatorial library" as used herein refers to a set of compounds that are made by the same process, by varying one or more of the reagents". The examiner maintains that the collections of compounds of the Palfreyman reference read on this definition. Applicant states that the compounds of the Palfreyman reference do not read on this definition because the compounds in the reference do not comprise a "set" and refer to certain, selected dictionary definitions of "set". However, the word "set" has a large number of definitions, the most common and general of which is a "group of things of the same kind that belong together and are so used" (see Webster's II, page 1067 which is made of record). The compounds of the Palfreyman reference read on this definition of "set". Note that claims must be given their broadest reasonable interpretation consistent with the specification. In re Hyatt, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Since the instant specification is silent as to the definition of "set", the most general definition of the term has been applied. The PTO applies to verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage, as they would be understood by one of ordinary skill in the art. Moreover, the instant specification clearly recites that combinatorial libraries may be made as *individual pure* compounds (page 7, line 17).

11. Also, as stated in the rejection, although Palfreyman et al does not disclose that their collections of compounds (i.e. libraries) are made by the claimed processes, the products of Palfreyman et al would appear to be the same as those recited by the instant claim, regardless of their method of manufacture. See MPEP 2113. Also note that many

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of the instant claims recite process limitations only and thus are non-limiting on the product. The collection of compounds of Palfreyman et al (reading on the claimed "combinatorial library") meet all of the limitations of the claimed library except for the product-by-process limitations and would either anticipate or render obvious the claimed library. "[E]ven though product-by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-byprocess claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The examiner respectfully points out that since the claim is drawn to a "combinatorial library", but this product is defined as a product-by-process, that any collection of compounds meeting the structural requirements of the instant claims reads on this product. The process by which the claimed library is made does not appear to lend patentable weight to the claimed invention. One of ordinary skill would expect the library to be the same no matter how it was synthesized. Applicant merely argues the different methods of production of libraries. The examiner's position is that the products of Palfreyman et al would appear to be the same as those recited by the instant claim, regardless of their method of manufacture. Again, the examiner respectfully points out that since the claim is drawn to a "combinatorial library", but this product is defined as a product-by-process, that <u>any</u> collection of compounds meeting the structural requirements of the instant claims reads on this product.

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12. For these reasons and the reasons of record, the above rejection under 35 U.S.C. 102/103 is maintained.

New Rejections --- Necessitated by Amendment Claim Rejections - 35 USC § 112

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claim 38 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The specification as originally filed does not provide support for the invention as now claimed. Claim 38 has been amended to recite that R⁹, R¹⁰ and R¹¹ can now be hydrogen, "provided that R¹⁰ and R¹¹ are not both hydrogen". There is simply no disclosure in the specification which specifically supports this negative limitation. Applicant points to only general teachings in the specification with respect to compounds that may fall within this definition. However, in order for a negative limitation to be added to a claim, that particular limitation must be *specifically recited* in the specification. See MPEP 2173.05(i): Any negative limitation or exclusionary proviso must have basis in the original disclosure. See *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), aff 'd mem.,

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738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion.

Status of Claims/Conclusion

- 15. No claims are allowed.
- 16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is

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(703) 308-0065. The examiner is on an increased flextime schedule but can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.

18. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached at (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D. November 10, 2003

MAURIE GARCUS TOMER PH.D. PRIMARY EX-MINER